

CLAIMS

The invention is claimed as follows:

1. A device for removing uremic toxins in a dialysis procedure
5 comprising:

a body having an inlet and an outlet and defining an interior, the interior including a layer comprising urease, a layer comprising zirconium oxide, a layer comprising zirconium phosphate, and a layer comprising carbon; and

10 the device being so constructed and arranged so that a fluid entering the device contacts the zirconium phosphate layer upon entering the device before contacting the urease or the zirconium oxide layer.

2. The device of Claim 1 wherein the zirconium oxide has been modified to remove the nitrate ion.

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3. The device of Claim 1 wherein the zirconium oxide is in hydroxyl form.

20 4. The device of Claim 1 wherein the carbon layer is located in juxtaposition to the outlet.

5. The device of Claim 4 wherein the fluid flows through a layer of zirconium oxide before entering the carbon layer.

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6. The device of Claim 1 wherein the zirconium phosphate has a pH of approximately 2 to about 8.

7. The device of Claim 1 wherein the zirconium oxide has a pH of approximately 6 to about 13.

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8. The device of Claim 1 including two separate layers of zirconium phosphate.

9. The device of Claim 1 including two separate layers of zirconium oxide.

5 10. The device of Claim 1 including an open header at each of the inlet and outlet end of the device.

11. The device of Claim 1 including an opening for venting a gas to the atmosphere located at the outlet end.

10 12. A cartridge for use in a dialysis system for removing toxins comprising:

a body having an inlet end and an outlet end;

15 an interior including at least four layers, the layers including a first layer of a resin selected from the group consisting of zirconium phosphate having a pH of approximately 2.5 to about 5 and urease, a second layer of a resin selected from the group consisting of zirconium oxide having a pH of approximately 9 to about 13 and urease, a third layer of zirconium phosphate, and a fourth layer of zirconium oxide having a pH of approximately 6.5 to about 7.5; and

20 the interior being so constructed and arranged that a fluid entering the interior from the first inlet end flows through the first layer, then the second layer, then the third layer, and then the fourth layer.

13. The cartridge of Claim 12 wherein the zirconium oxide has been 25 modified to remove a nitrate ion and substitute bicarbonate ion therefor.

14. The cartridge of Claim 12 wherein the zirconium oxide is in hydroxyl form.

30 15. The cartridge of Claim 12 including a carbon layer located in juxtaposition to the outlet end.

16. The device of Claim 12 wherein the first layer comprises approximately 200 to about 800 grams of zirconium phosphate.

17. The device of Claim 12 wherein the fourth layer comprises 5 approximately 50 to about 200 grams of carbon.

18. The device of Claim 12 wherein the urease is a cross-linked enzyme crystal urease.

19. A device for regenerating a dialysis solution comprising:
10 a body including a resin bed; and
the resin bed including at least a layer of urease, zirconium phosphate, zirconium oxide, and carbon and being so constructed and arranged that a dialysis solution having a pH that is either basic or acidic will exit the cartridge after it passes through the resin bed at a pH of approximately 7 to about 7.8.

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20. The device of Claim 19 wherein the first layer of the resin bed that the solution contacts is selected from the group consisting of zirconium phosphate having a pH of approximately 2.0 to about 5 and urease.

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21. The device of Claim 19 wherein the second layer that the solution passes through in the resin bed is selected from the group consisting of zirconium oxide having a pH of approximately 9 to about 13 and urease.

22. The device of Claim 19 wherein the third layer of the resin bed that 25 the solution contacts is zirconium phosphate.

23. The device of Claim 19 wherein the fourth layer of the cartridge that the solution contacts is zirconium oxide having a pH of approximately 6.8 to about 7.5.

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24. The device of Claim 19 wherein the pH of the solution exiting the cartridge is approximately 7.4.

25. The device of Claim 19 wherein the first layer comprises approximately 200 to about 800 grams of zirconium phosphate.

5 26. The device of Claim 19 wherein the carbon layer removes less than 30 grams of glucose from a dialysis solution.

27. The device of Claim 19 wherein the urease is a cross-linked enzyme crystal urease.

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28. A device for use in a system for treating a patient with a dialysis solution comprising:

an inlet in fluid communication with a source of dialysis solution;

a body including the inlet and defining an interior and having an outlet;

15 the body comprising a resin bed comprising a layer of urease, a layer of zirconium oxide, and a layer of zirconium phosphate that define a three layer structure; and

the resin bed being oriented so that the first layer that the dialysis solution contacts of the three layer structure is either the urease or the zirconium phosphate

20 layer and the zirconium oxide layer is so constructed and arranged that a basic or an acidic dialysis solution entering the inlet will exit the outlet with a physiologically acceptable pH.

29. The device of Claim 28 wherein the device is used in a regenerative dialysis system.

30. The device of Claim 28 wherein the first layer of the resin bed that the solution contacts is selected from the group consisting of zirconium phosphate having a pH of approximately 2.0 to about 5 and urease.

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31. The device of Claim 28 wherein the second layer that the solution passes through in the resin bed is selected from the group consisting of zirconium oxide having a pH of approximately 9 to about 13 and urease.

5 32. The device of Claim 28 wherein the resin bed includes at least four layers.

33. The device of Claim 28 wherein the zirconium oxide layer has a pH of approximately 6.8 to about 7.5.

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34. The device of Claim 28 wherein the pH of the solution exiting the cartridge is approximately 7.2-7.6.

15 35. The device of Claim 28 wherein the first layer comprises approximately 200 to about 800 grams of zirconium phosphate.

36. The device of Claim 28 including a layer of carbon that is selected so that it does not remove an excess amount of glucose.

20 37. A method for constructing a cartridge for use in a system for providing dialysis comprising the steps of providing a resin bed including zirconium oxide and zirconium phosphate and selecting and orienting the layers of zirconium oxide and zirconium phosphate to allow the resin bed to remove uremic toxins present in a dialysis solution entering the resin bed and causing a dialysis solution 25 exiting the cartridge to have a physiological pH and include a physiological acceptable electrolyte balance.

30 38. The method of Claim 37 including the steps of providing a body having an inlet and an outlet and defining an interior, the interior including a layer comprising urease, a layer comprising zirconium oxide, a layer comprising zirconium phosphate, and a layer comprising carbon; and the device being so constructed and arranged so that a fluid entering the device contacts the zirconium

phosphate layer upon entering the device before contacting the urease *on* the zirconium oxide layer.

39. The method of Claim 37 wherein the zirconium phosphate has a pH 5 of approximately 2 to about 8.

40. The method of Claim 37 wherein the zirconium oxide has a pH of approximately 6 to about 13.

10 41. The method of Claim 37 including two separate layers of zirconium phosphate.

42. The method of Claim 37 including two separate layers of zirconium oxide.

15 43. The method of Claim 37 wherein the resin includes approximately 200 to about 800 grams of zirconium phosphate.

20 44. The method of Claim 37 wherein the resin bed includes approximately 50 to about 200 grams of carbon.

45. The method of Claim 38 wherein the urease is a cross-linked enzyme crystal urease.

25 46. A method for providing dialysis comprising the steps of passing a dialysis fluid through a body having an inlet and an outlet and defining an interior, the interior including at least four layers, a first layer comprising zirconium phosphate having a pH of approximately 2.5 to about 5 or urease, a second layer comprising zirconium oxide having a pH of approximately 9 to about 13 or urease, a 30 third layer comprising zirconium phosphate and a fourth layer comprising zirconium oxide having a pH of approximately 6.8 to about 7.5.

47. The method of Claim 46 wherein the fourth layer of the body that the solution contacts is zirconium oxide having a pH of approximately 6.8 to about 7.5.

48. The method of Claim 46 wherein the body includes two separate
5 layers of zirconium oxide.

49. The method of Claim 46 wherein the zirconium oxide is in bicarbonate form.

10 50. The method of Claim 46 wherein the zirconium oxide is in hydroxyl form.

51. The method of Claim 46 wherein the body includes a carbon layer located in juxtaposition to the outlet end.

15 52. The method of Claim 46 wherein the first layer comprises approximately 200 to about 800 grams of zirconium phosphate.

20 53. The method of Claim 46 wherein the fourth layer comprises approximately 50 to about 200 grams of carbon.

54. The method of Claim 46 wherein the urease is a cross-linked enzyme crystal urease.

25 55. A method of providing regenerative dialysis comprising the step of removing at least some uremic toxins by passing a dialysis fluid through a body having an inlet and an outlet and defining an interior, the interior including at least four layers, a first layer comprising zirconium phosphate having a pH of approximately 2.5 to about 5 or urease, a second layer comprising zirconium oxide
30 having a pH of approximately 9 to about 13 or urease, a third layer comprising zirconium phosphate and a fourth layer comprising zirconium oxide having a pH of approximately 6.8 to about 7.5.

56. The method of Claim 55 wherein the pH of the dialysis fluid as it exits the body is approximately 7.4.

5 57. The method of Claim 55 wherein prior to entering the body of the pH of the dialysis fluid is acidic.

58. The method of Claim 55 wherein prior to entering the body the pH of the dialysis fluid is basic.